



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3353]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0659. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Antimicrobial Animal Drug Distribution Reports and Recordkeeping--21 CFR 514.87

OMB Control Number 0910-0659--Extension

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) to submit to FDA an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. Sponsors are also required to maintain distribution records for their animal drug products, including separate information for each month of the calendar year, under section 512(l)(3) of the FD&C Act. These provisions were enacted to assist FDA in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance.

Section 514.87 of our regulations (21 CFR 514.87) codifies the reporting requirements established in the FD&C Act. Sponsors submit antimicrobial animal drug sales and distribution reports to the Agency on Form FDA 3744. Each report must specify: (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. Each report must also provide a species-specific estimate of the

percentage of each product that was sold or distributed domestically in the reporting year for use in cattle, swine, chickens, or turkeys for such species that appear on the approved label.

Collection of information on the amount of animal antimicrobials being distributed, including species-specific information, is necessary to support our ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animals and humans. We intend to use these data to supplement existing information, including data collected under the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System programs. Data from multiple sources are needed to provide a comprehensive and science-based picture of antimicrobial drug use and resistance in animal agriculture.

In the *Federal Register* of October 1, 2018 (83 FR 49395), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
514.87(a) through (e)--Annual Reports for Sponsors With Active Applications--Paper Submission	3744	10	7.5	75	62	4,650
514.87(a) through (e)--Annual Reports for Sponsors With Active Applications--Electronic Submission	3744	10	7.5	75	52	3,900
514.87(a) through (e)--Annual Reports for Sponsors With Inactive Applications--Paper Submission	3744	4	26.5	106	2	212

21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
514.87(a) through (e)-- Annual Reports for Sponsors With Inactive Applications-- Electronic Submission	3744	3	35	105	2	210
Total						8,972

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate that 20 sponsors will have active applications, and we assume that half of the respondents will report electronically, while the other half will report on paper. We estimate that 10 sponsors with active applications will spend 62 hours annually to assemble the necessary information, prepare, and submit an annual antimicrobial animal drug sales and distribution report on paper, and 10 sponsors with active applications will spend 52 hours annually to assemble the necessary information, prepare, and electronically submit an annual antimicrobial animal drug sales and distribution report. We estimate that seven sponsors will have inactive applications, and we assume that half of these respondents will report electronically, while the other half will report on paper. We estimate that sponsors with inactive applications will spend 2 hours to prepare their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

Table 2--Estimated Annual Recordkeeping Burden¹

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	27	1	27	2	54

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910-0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910-0139), manufacturers currently are required to maintain distribution records that include dosage form and the date the drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 54 hours for further compliance with section 512(l)(3) of the FD&C Act, as detailed in table 2.

Based on a review of the information collection since our last request for OMB approval, which was submitted with a final rule, we have made no adjustments to our burden estimates as reported in tables 1 and 2, other than to remove the one-time burden of 787 hours, which represented the time needed to review the provisions of the final rule and develop a compliance plan in the first year of compliance.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-09425 Filed: 5/7/2019 8:45 am; Publication Date: 5/8/2019]